Time Critical Diagnosis—Stroke and STEMI System Implementation

Meeting Four, January 6, 2009

ATTENDEES:

Dr. Samar Muzaffar, Department of Health and Senior Services (DHSS); Paula Adkison, DHSS; Jennifer Aiken, Centerpoint Medical Center; Mark Alexander, CoxHealth; Lisa Archer, Northeast Regional Medical Center; Dr. Dmitri Baklanov, University of Missouri Hospital and Clinic; Dave Barringhaus, Physio-Control; Steve Bassett, Ozarks Medical Center; Jack Bates, Air Evac Lifeteam; Carol Beal, St. John's Regional Health Center; Anita Berwanger, DHSS; Nancy Bettasso, St. John's Regional Medical Center; Jennifer Bjelich, St. John's Health System; Wes Boles, Christian Hospital EMS; Barbara Brendel, DHSS; Linda Brown, Southeast Missouri Hospital; Jo-Ann Burns, Barnes-Jewish Hospital; Dr. W. Stephen Casady, Putnam County Hospital; Donna Cash, North Kansas City Hospital; Dr. Douglas Char, Washington University School of Medicine; Angela Christesen, Salem Memorial District Hospital; Doug Clark, Herman Area EMS; John Clemens, Marion County Ambulance District; Karen Connell, DHSS; Monti Cooper, Southeast Missouri Hospital; Dr. Jeff Coughenour, University Hospital and Clinics; Adrianne Courter, I-70 Medical Center; Dr. Salvador Cruz-Flores, St. Louis University Hospital; Mike D'Agostino, Metropolitan Ambulance Service Trust; Rich Dandridge, Warren County Ambulance District; Susan Davis, St. John's Mercy Medical Center; Linda Dean, Freeman Health System; Liz Deken, American Heart Association; Lisa Donnelly, St. Luke's Hospital; Mary Jo Draper, The Vandiver Group; Valerie Dutcher, Heartland Regional Medical Center; Ellen Ehrhardt, DHSS; Dr. Michael Farrar, North Kansas City Hospital; Jay Faulkner, Osage Beach Ambulance; Kelly Ferrara, The Vandiver Group; Cindy Feutz, University of Missouri Hospital and Clinics; Shirley Gastler, DHSS; Dolly Giles, Pike County Memorial Hospital; Martha Gragg, Missouri Foundation for Health; Michael Graves, North Kansas City Hospital; Gina Gregg, Research Medical Center; Paul Guptill, Missouri Hospital Association; Dr David Gustafson, Independence; Robin Hamann, American Heart Association; Dr. Kathryn Hedges, Lee's Summit Medical Center; Sean Hill, Linn County Ambulance District; Tom Holloway, Missouri State Medical Association; Sherri Homan, DHSS; Sara Howard, The Vandiver Group; Tracy Howard, Centerpoint Medical Center; Lindy Huff, St. Luke's Hospital; Jody Hyman, DHSS; Debbie Jacobson, Audrian Medical Center; Stacey Jett, Boone Hospital; Leeann Johnson, Staff for Life Helicopter; Freida Juliano, Hannibal Regional Hospital; Melissa Kaufman, Audrain Medical Center; Daniel Kernebeck, St. Louis University Hospital, Shelleen King, St. Luke's Brain and Stroke Institute; Jerry Kirchhoff, Air Evac Lifeteam; Mary Kleffner, DHSS; Dr. Michael Klevens, St. Luke's Hospital; Brenda Knight, Putnam County Memorial Hospital; Ken Koch, St. Charles County Ambulance District; Cheryl Kyle, University Hospital and Clinics; Carol Lacy, Salem Memorial Hospital; Michael Lambert, University of Missouri Health Care; Michelle Leassner, Des Peres Hospital; Katie Liberto, Physio- Control; Dr. Michael Lim, Saint Louis University; Bonnie Linhardt, American Heart Association; Dean Linneman, DHSS; Jason Lynch, St. John's Mercy Medical Center; Colin McCoy, St. Louis Fire Department; Bryant McNally, Missouri Hospital Association; Dr. Steve Marso, Cardiovascular Consultants; Kaisey Martin, DHSS; Chris Medlin, Capital Region Medical Center; Bill Meeker, Laredo Fire Department; Ruby Mehrer, Lifeflight Eagle; Taz Meyer, St. Charles County Ambulance District; George Miller, State Fire Marshall, Boone County Fire Protection District; Michelle Miller, Missouri Foundation for Health; Eric Mills, University Hospital Ambulance Service; Lori Motley, Audrain Medical Center and Van-Far Ambulance District; Greg Natsch, DHSS; Carol Nierling, University of Missouri Hospital and Clinic; Tony Nunn, St. Luke's Hospital of Kansas City; Peggy Parks, Northeast Regional Medical Center; William Pearman, Chariton County Ambulance District; Marie Peoples, DHSS; Cynthia Peters, St. Mary's Medical Center; Joe Piskulic, Jefferson Memorial Hospital; Debbie Playter, Audrain Medical Center; Jeff Probus, Adair County Ambulance District; Sharon Pulver, St. Joseph Health Center; Pam Ragan, Cedar County Memorial Hospital; Dave Reed, Adair County Ambulance District; Dr. Danelle Richards, St. John's Hospital-Lebanon; Lisa Riggs, St. Luke's Health System; Connie Roberts, Putnam County Memorial Hospital; Dr. Joseph Salomone, Kansas City EMS Medical Director; Twany Sandifer, Capital Region Medical Center; Nancy Schuenemeyer, Boone Hospital Center; Chris Schulze, CoxHealth; Barb Seagrass, Des Peres Hospital; Heather Seemann, SSM St. Joseph Hospital of Kirkwood; Dr. Allyn Sher, Boone Hospital; Dr. Niranjan Singh, University of Missouri School of Medicine; Chip Smack, Christian Hospital; Andrew Spain, University of Missouri Hospital and Clinics; Edward Spain, St. John's Regional Health Center; Debby Sprandel, St. Francis Medical Center; David Stagner, St. Francis Medical Center; Chad Staley, Montgomery

County Ambulance District; Mickey Stout, St. John/s Hospital – Lebanon; Debbie Summers, St. Luke's Brain and Stroke Institute; Daniel Thompson, HCA Healthcare; Dr. Alan Umbright, SSM St. Joseph, St. Charles; Kathy Vickery, Southeast Missouri Hospital; Phyllis Vos, Research Medical Center; Myrna Ward, Southeast Missouri Hospital; Jim Waring, Wheeler Heart and Vascular Center, Terri Waters, The Vandiver Group; Marilyn Welling, St. John's Regional Medical Center; Jeff Wilson, North Kansas City Hospital; Amy Wood, American Heart Association; Steve Woods, Des Peres Hospital; Monroe Yancie, St. Louis Fire Department; and Beverly Smith, DHSS.

General Information

A total of 135 people attended the fourth meeting of the Time Critical Diagnosis (TCD) Stroke and STEMI System implementation process. Dr. Muzaffar provided an overview of where the group is in the process of establishing stroke and STEMI centers in Missouri. Dr. Duff, the lead for the Stroke Work Group, has resigned and his position will be assumed by Dr. Rymer from St. Lukes Hospital in Kansas City. A representative from the Centers for Disease Control and Prevention (CDC), the Heart Disease and Stroke Prevention Division will participate in the next meeting on February 10, 2009. A portion of the funding for support of the Time Critical Diagnosis Stroke and STEMI System comes from CDC.

Out-of-Hospital and Stroke Hospital Groups

Ken Koch provided an overview of the steps of the process from calling 911, directing call to primary or secondary Public Safety Answering Points (PSAP), managing the call by Emergency Medical Dispatch (EMD) personnel (using protocol and guidelines from the Medical Priority Dispatch System, Association of Public Safety-Communication Officials or Powerphone) , activating the ambulance service, assessing and triaging the patient by Emergency Medical Services (EMS) personnel, communicating assessment information to the hospital, to finally transporting patient to appropriate facility. At each stage of this process there are laws, regulations and/or guidelines for the provision of dispatch, patient assessment, and triage and transfer services in an appropriate and timely manner. Understanding these existing steps and protocols is crucial to identify where changes will advance care through these components of the system and improve overall outcomes.

The group discussed the key information that EMS should provide to hospital personnel regarding suspected stroke patients. They agreed that EMS should obtain vital signs, including 12-lead EKG and a brief history (last time seen normal or without symptoms). It was also recommend that a phone number where family, knowledgeable of the patient's current condition and health history, can be contacted immediately (preferably a cell phone).

Treatment by EMS personnel for stroke patients in transport was believed fairly standard. This includes administration of appropriate level of oxygen and adjusting position of the head (flat vs. 30^{o} elevated) to protect airways. At this time literature supports both head positions so need recommendation from clinicians for treatment protocol regarding this issue.

It was recommended that a paramedic be in attendance with EMS runs but there are circumstances when this is not possible. The vast majority of ambulance services in Missouri (approximately 200+) operate at the Advance Life Support level (ALS) but a few services (approximately 10) have only Basic Life Support (BLS) capacity. The group discussion reflected that it would be impractical to have all services at the ALS level.

Another issue discussed related to the ambulance service having authority to bypass a local hospital if it could not provide the level of care the patient requires. The group requests a legal review of this issue.

Currently there is no protocol for transporting patients from one hospital to another hospital and it was requested that the stroke hospital group establish this. This was considered a priority item. It was also requested that the hospital stroke group make recommendations on professional education for EMS personnel. In general, the group wants to keep protocols broad to allow hospitals the needed flexibility to meet needs of patients within the region.

Out-of-Hospital Work Group

The group discussed assessment tools that EMS personnel could use with stroke patients. While the original task force recommended the use of one tool, this group believed that it was acceptable to allow use of several tools. Three specific stroke scales and the National Institutes of Medicine scale and guidelines were reviewed and the majority of the group preferred the use of the Cincinnati stroke scale. This would be the scale initially recommended but it was further recommended that data be collected on all of the scales in order to devise a Missouri-specific scale that adopts the best of all scales into one tool for future use. There was also agreement that, while there could be a variance allowed on a statewide basis for use of stroke scales, each region should be consistent in the use of a single scale to minimize confusion. The group also recognized that scales will change over time and believed that the American Heart Association and American Stroke Association have expertise in assessing stroke exams and assessment tools. Missouri could recommend that a scale in use be approved by these organizations as long as it is consistent within the region.

The out-of-hospital group began discussion on the STEMI assessment-triage protocol. There was debate regarding whether the Emergency Medical Technician

(EMT) should read the EKG or just transmit the information. General intent is to forward results to hospital for physician to interpret.

Stroke Work Group

The work group reviewed professional education requirements for stroke centers. Discussion was also begun on Telemedicine issues for support of stroke care. There is concern that the current busy schedules of neurologists make it difficult for them to expand their services through telemedicine.

Regulation Work Group--Stroke

The regulation work group began review and discussion of the draft of the proposed regulations for stroke. Based on the work of the Stroke Work Group, Department staff compiled a document that outlines the criteria the work group recommends and cross-references it with the proposed regulations. The Proposed Regulations for Stroke Centers is attached (attachment 1) with changes noted based on the discussion at this meeting.

STEMI Work Group

Sherri Homan, PhD, RN, Chronic Disease Epidemiologist, provided an overview of *Quality Outcomes for Hospital Percutaneous Coronary Intervention***.** She reviewed relevant literature related to the criteria being discussed by the work group. This review included the relation of volume of Percutaneous Coronary Interventions (PCI) to outcomes, current practice standards, and variables that contribute to better outcomes. She also did a review of Missouri data that shows care patterns by regions, volume of PCI being reported by Missouri hospitals, and Missouri heart disease profile data available on-line. Her presentation is available on the Department's website, http://www.dhss.mo.gov/TCD_System/Implementation.html.

Dr. Muzaffar summarized select data and literature. There are about 50 hospitals doing PCI and Primary PCI (PPCI) in Missouri and each EMS region has at least one hospital that would qualify for Level I based on the currently proposed volume criteria (≥ 400 total PCIs and > 49 PPCIs). Currently no data was available on the treatment times (from symptom onset or entry into the hospital—door to balloon (D2B) time for PCIs—to definitive care) and availability of surgical back-up for these centers. Dr. Muzaffar also reviewed recommendations that Level IV centers not be included in the STEMI system of care, as Level III centers would be providing thrombolytics then transferring to

a higher level of care as appropriate. The range of care needs for STEMI patients, at this time, can be managed in a system with three levels of center designation.

The work group extensively discussed STEMI Center volume. The group discussed the reasoning for higher PCI volumes for Level I centers compared to requirements for Level II centers. The group eliminated the "Annual hospital STEMI Patient Volume" criteria as it was not relevant to Missouri at this time on the attached STEMI Criteria Framework (attachment 2).

The argument was made that requiring "49 PPCI procedures/year/ center" for Level I did not have strong evidence to support this criteria in Missouri. There was general agreement that evidence strongly supported 36 PPCIs/year/center for Level II centers. The group agreed that Level II centers must be able to provide the recommended standard of care documented by the evidence.

Further discussion on the PPCI requirements revealed that the group supported a differentiation between Level I and II for this indicator, and that it should be higher than 36. The two higher levels discussed included >75 and > 49 PPCI/year/level I center. It was mentioned that 75 may be too high to be realistic and would limit Level I to very few centers at this time. The number of PPCIs for Level I centers was voted upon. Fourteen wanted 75; nineteen wanted 49, and seven wanted $\geq$36.

Other changes made on the criteria included:

- The group decided that operator volume does not belong under "STEMI Center Volume Criteria", because it is not a center criterion. The indicator, "75+ PCI procedures/year/physician", was moved to the "Personnel Education/Credentials" section.

- Discussion on "STEMI Center Hospital Capabilities" included #1b, the qualifications for the STEMI Program Manager. This was changed from "RN" to "RN or other qualified individual" to go along with common practice.

- Under "Time Frame for availability of services", it was decided that 3b., "24/7 CATH Lab" and 3d., "angiography and intervention capabilities available 24/7" should be promptly available for both Level I and II while omitted for Level III; (3b. and 3d. were combined). #3c, "24/7 CABG" was changed from immediately available to promptly available for Level I.

- #4, "24/7 clinical laboratory to provide necessary testing and results" was changed from immediately available to required for all three levels. #5 was changed to "one call cath lab team activation" required for level I and II, and the group added "one call access for STEMI transfer" as a requirement for Level III.

- Under "Hospital Protocol for rapid transfer from non-PCI facility", #2 was clarified that STEMI transfer agreements must be in writing. The group removed requirement for #3, "rapid transfer process" from Level I as there is no higher level to transfer to. Under #4, "hospital diversion protocol", the group added that state law will be followed.

- Under "Hospital capacity to support STEMI patient discharge transition back to community, timely feedback for sending and receiving facilities", the group deleted the requirement to "call within 24 hours with written notice within 72 hours" because it was not always realistic, even though important.

- Under "Professional Education/Credentials", added #7 regarding "75+ PCI/year for intervention cardiologist" as a requirement for Level I and II.

- Under "Performance Metrics" group decided to delete first line of #1, "PCI within 60+/- minutes of arrival (75 – 80% of the time)" to "PCI within 90 minutes of field ECG diagnosis or first medical contact (75% of the time)."

The STEMI workgroup will resume discussion at the next meeting with #2 under "Performance Metrics".

Meeting Closure

Representatives from each group presented an overview of what has been completed by their respective work group to date based on the work plans that were established at the September 2008 meeting.

Out-of-Hospital Work Group

Complete:

- Pre-hospital Protocol
- Stroke Protocol
- Stroke Assessment tool
- All issues reviewed from regional perspective with recommendation for need for flexibility on statewide basis with consistency on regional level

Work Remaining

- STEMI protocol
- Professional Education recommendations
- Plan to inform hospitals and health community about TCD and designation Process

Stroke Work Group

Complete:

- Criteria for stroke center designations
- Draft regulations

Work Remaining:

- Hospital-to-hospital transfer protocol
- Professional education recommendations
- Telemedicine
- Plan to inform hospitals and health community about TCD and designation Process

STEMI Work Group

Complete:

- Near final review of criteria for center designation

Work Remaining

- Finalize center designation criteria
- Professional education recommendations
- Hospital-to-hospital transfer protocol
- Plan to inform hospitals and health community about TCD and designation Process

Regulation Work Group

Began:

- Review of draft stroke center designation regulations

Work Remaining:

- Complete review and finalize draft of stroke regulations
- Review and finalize draft of STEMI regulations

Attachment 1-Draft Proposed Regulations for Stroke Center Designation

Discussed 1/6/09

Title 19 - DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30 - Division of Regulation and Licensure
Chapter 40 – Comprehensive Emergency Medical Services Systems Regulations

PROPOSED REGULATIONS

Key

Red-Core issue that links with stroke center criteria in *Stroke Center Designation – Cross Walk*. This document is on Department website under 1/6/09 meeting listing http://www.dhss.mo.gov/TCD_System/Implementation.html

Blue-Changes discussed 1/6/09

19 CSR 30-40.XXX Standards for Stroke Center Designation.

PURPOSE: This amendment

EDITOR'S NOTE: I-R, II-R, III-R or IV-R after a standard indicates a requirement for level I, II III, or IV stroke center respectively. I-IH, II-IH, III-IH after a standard indicates an in-house requirement for level I, II or III stroke center respectively.
I-IA, II-IA, III-IA, or IV-IA indicates an immediately (20 minutes) available requirement for level I, II, III or IV stroke center respectively. I-PA, II-PA, III-PA or IV-PA indicates a promptly (30 minutes) available requirement for level I, II or III stroke center respectively.

PUBLISHER'S NOTE: The Secretary of State has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) General Standards for Stroke Center Designation.

(A) The hospital board of directors, administration, medical staff and nursing staff shall demonstrate a commitment to quality stroke care. Methods of demonstrating the commitment shall include, but not be limited to, a board resolution that the hospital governing body agrees to establish policy and procedures for the maintenance of services essential for a stroke center; assure that all stroke patients will receive medical care at the level of the hospital's designation; commit the institution's financial, human and physical resources as needed for the stroke program; and establish a priority admission for the stroke patient to the full services of the institution. (I-R, II-R, III-R IV-R)

3

1. **Stroke centers shall meet national guidelines as established by national organizations including, but not limited to the Joint Commission, the American Stroke Association and the Brain Attack Coalition (I-R, II-R, III-R).**

(B) Stroke centers and participating hospitals shall agree to accept all stroke victims appropriate for the level of care provided at the hospital, regardless of race, sex, creed or ability to pay. (I-R, II-R, III-R, IV-R)

(C) The stroke center ~~hospital~~ shall demonstrate evidence of a stroke program through which professional staff ~~with a Stroke Team that has appropriate experience to~~ maintain skill and proficiency in the care of stroke patients.

1. Such evidence shall include:
    A. A Stroke Team; (I-R/IA, II-R/IA III-R/IA)
    B. Meeting continuing education requirements by professional staff; (I-R/IA, II-R/IA III-R/IA IV-R/IA)
    C. Documented regular attendance of core neurologists and representation from appropriate medical staff, such as neurosurgeons, emergency medicine physicians and anesthesiologists at stroke program performance improvement and patient safety program meetings. Regular attendance shall be defined by each stroke service, but shall be not less than fifty percent (50%) of all meetings; (I-R/IA, II-R/IA, III-R/IA)
    D. Documentation of continued experience as defined by the stroke Medical Director in management of sufficient numbers of stroke patients to maintain skill levels. The stroke medical director must ensure and document dissemination of information and findings from the peer review meetings to the non-core stroke team members on the stroke call roster; (I-R/IA, II-R/IA) and
    E. Outcome data on quality of patient care as identified for study by Emergency Medical Services regions. (I-R/IA, II-R/IA III-R/IA IV-R/IA) **1, 2, 5, 6, 7, 11, 19, 21**
2. The designated stroke team shall be available 24 hours per day and consist of, but not limited to:
    A. Physician experienced in diagnosing and treating cerebrovascular disease
    B. Another health care professional, (i.e.) nurse, physician's assistant, nurse practitioner. (I-R/IA, II-R/IA III-R/IA IV-R/IA) **2, 6, 7**

END POINT-1/6-09

3. The expanded multidisciplinary team shall include an appropriate representative from hospital administration, emergency medical services, emergency department, stroke ICU, pharmacy, CT/radiology, stroke unit, rehabilitation, discharge planning, nutritional services and laboratory. (I-R, II-R, III-R) **19, 23**

(D) There shall be a lighted designated helicopter landing area at the stroke center to accommodate incoming medical helicopters. (I-R, II-R, III-R IV-R)

1. The landing area shall serve solely as the receiving and take-off area for medical helicopters and shall be cordoned off at all times from the general public to assure its continual availability and safe operation. (I-R, II-R, III-R IV-R)
2. The landing area shall be on the hospital premises no more than three (3) minutes from the emergency room. (I-R, II-R, III-R IV-R)

(E) The hospital shall appoint a board-certified physician, including, but not limited to three of the following:

1. Board certified neurologist or vascular neurosurgeon with a stroke fellowship, or neurocritical care fellowship, or vascular neurosurgery fellowship or equivalent experience
2. Board certified in vascular neurology or neurocritical care
3. Fellow of the Stroke Council of the AHA
4. Clinician who diagnoses and treats at least 50 patients with cerebrovascular disease annually or more than 50% of his/her time is dedicated to the care of cerebrovascular patients and/or research on cerebrovascular disease
5. Clinician with at least 10 peer-reviewed publications dealing with cerebrovascular disease

(F) Clinician with at least 12 CME credits each year in areas directly related to cerebrovascular disease to serve as the stroke medical director. (I-R, II-R, III-R) **5**

1. There shall be a job description and organization chart depicting the relationship between the stroke medical director and other services. (I-R, II-R, III-R IV-R) **5**

2. The stroke medical director shall be a member of the stroke team call roster. (I-R, II-R, III-R IV-R) **5, 7**

3. The stroke medical director shall be responsible for the oversight of the education and training of the medical and nursing staff in stroke care. (I-R, II-R, III-R IV-R**) 5, 11**

4. The stroke medical director shall document a minimum average of twelve (12) hours of continuing medical education (CME) in cerebrovascular disease every year. (I-R, II-R, III-R IV-R) **5, 11**

5. The stroke medical director shall participate in the stroke center's research and publication projects. (I-R) **5, 18**

6. The hospital shall appoint a physician to serve as the stroke medical director. IV-R

(G) There shall be a stroke program manager who is a registered nurse. (I-R, II-R, III-R IV-R) **16**

1. There shall be a job description and organization chart depicting the relationship between the stroke program manager and other services. (I-R, II-R, III-R IV-R)

2. The stroke program manager shall document a minimum average of ten (10) hours of continuing nursing education in cerebrovascular disease every year and attend one national or regional meeting every other year that focuses on some aspect of cerebrovascular disease. (I-R, II-R, III-R IV-R) **11, 16**

(H) All members of the stroke team call roster and emergency medicine physicians shall document a minimum average of eight (8) hours of CME in cerebrovascular disease every year**.** (I-R, II-R, III-R IV-R) **7, 11**

(I) There shall be a specific and well-organized system for rapidly notifying and activating the stroke team to evaluate patients presenting with symptoms suggestive of an acute stroke. (I-R, II-R, III-R IV-R) **2, 7**

(J) Level III or Level IV stroke centers shall have a call roster providing 24 hour a day backup neurology coverage or networking agreement with Level I or Level II stroke center for telephone consult or telemedicine when a neurologist is not available. The Level III or IV shall have an expedited transfer agreement with the Level I or Level II stroke center. **2, 4, 8**

(K) Rehabilitation services shall be directed by a physician with board certification in physical medicine and rehabilitation or by other properly trained individuals (i.e., neurologist experienced in stroke rehabilitation. (I-R, II-R) **17**

(L) Consults for physical medicine and rehabilitation, physical therapy, occupational therapy, and speech therapy shall be requested and completed within 24 hours of admission. (I-R, II-R) **2, 17**

(M) The hospital shall demonstrate that there is a plan for adequate post-discharge follow-up on stroke patients, including rehabilitation. (I-R, II-R, III-R) **17, 23**

(N) Hospital shall keep stroke team log which contains the following: (I-R, II-R, III-R IV-R)

1. Response times
2. Patient diagnosis
3. Treatment/actions
4. Outcomes (I-R, II-R, III-R IV-R) **1, 7**

(O) A Missouri stroke registry shall be completed on each stroke patient and meets the following criteria: Includes at least one (1) code within the range of the following diagnostic codes as defined in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9)-(CM) XXX-XXX which is incorporated by reference in this rule as published by the Centers for Disease Control and Prevention in 2006 and is available at National Center for Health Statistics, 1600 Clifton Road, Atlanta, Georgia 30333. This rule does not incorporate any subsequent amendments or additions and must include one of the following criteria: hospital admission, or patient transfer out of facility or death resulting from the stroke (independent of hospital admission or hospital transfer status.) The registry shall be submitted electronically in a format defined by the Department of Health and Senior Services. Electronic data shall be submitted quarterly, ninety (90) days after the quarter ends. The stroke registry must be current and complete. A patient log with admission date, patient name, and diagnosis must be available for use during the site review process. Information provided by hospitals on the stroke registry shall be subject to the same confidentiality requirements and procedures contained in section 192.067, RSMo. (I-R, II-R, III-R IV-R) **1**

(P) The hospital shall have a one-call stroke team activation protocol. This protocol will establish the following.

1. The criteria used to rank stroke patients according to time of symptom onset
2. Identifies the persons authorized to notify stroke team members when a suspected stroke patient is en route or has arrived at the stroke center. (I-R, II-R, III-R IV-R) **7, 10**
3. The one-call stroke team activation protocol shall provide for immediate notification and response requirements for stroke team members when a suspected stroke patient is en route to the stroke center. (I-R, II-R, III-R IV-R) **2, 7, 10**

(Q) The hospital shall have a plan to notify an organ or tissue procurement organization and cooperate in the procurement of anatomical gifts in accordance with the provisions in section 194.233, RSMo. (I-R, II-R, III-R IV-R)

(R) There shall be no level III or IV stroke centers designated within fifteen (15) miles of any Missouri level I or II stroke center.

(2) Hospital Organization Standards for Stroke Center Designation.

(A) There shall be a delineation of privileges for the neurologists/neurosurgeons made by the medical staff credentialing committee. (I-R, II-R, III-R) **6, 11**

(B) All members of the stroke team call roster shall comply with the availability and response requirements per the hospital protocol. If not on the hospital premises, stroke team members who are immediately available shall carry electronic communication devices at all times to permit contact by the hospital and shall respond immediately to a contact by the hospital. (I-R, II-R, III-R, IV-R) **2, 7, 10**

(C) Physicians who are board-certified or board-admissible and who are credentialed by the hospital for stroke care shall be on the stroke center staff and be available as indicated.

1. Neurology—I-R/IA, II-R/IA, III-R/PA **6, 11**
   A. The neurology staffing requirement may be fulfilled by a senior neurology resident credentialed in neurology. **6, 11**
   B. The neurologist shall be immediately available and in attendance with the patient when a neurology resident is fulfilling availability requirements. **2, 6**
2. Neurologic surgery—I-R/IA, II-R/IA **2, 6**

A. The neurologic surgery staffing requirement may be fulfilled by a surgeon who has been approved by the chief of neurosurgery for care of stroke patients. **6, 11**
B. The surgeon shall be capable of initiating measures toward stabilizing the patient and performing diagnostic procedures. **6**
C. In a level I or II stroke center call rosters providing back-up neurosurgeon coverage will be maintained. **6**

3. Emergency medicine—I-R/IH, II-R/IH, III-R/IH IV-R/IA **2, 13**
4. Neuro Endovascular specialist—I-R/IA **6**
5. Diagnostic Radiology—I-R/PA, II-R/PA, III-R/PA **2, 12**
6. Anesthesiology—I-IH, II-R
   A. Anesthesiology staffing requirements may be fulfilled by anesthesiology residents or certified registered nurse anesthetists (CRNA), or anesthesia assistants capable of assessing emergent situations in stroke patients and of providing any indicated treatment including induction of anesthesia. When anesthesiology residents, anesthesia assistants or CRNA's are used to fulfill availability requirements, the staff anesthesiologist on call will be advised and promptly available and present for all operative interventions and emergency airway conditions. The CRNA may proceed with life preserving therapy while the anesthesiologist is en route under the direction of the neurosurgeon, including induction of anesthesia.

(3) Standards for Special Facilities/Resources/Capabilities for Stroke Center Designation.

(A) The hospital shall meet emergency department standards for stroke center designation.

1. The emergency department staffing shall ensure immediate and appropriate care of the stroke patient. (I-R, II-R, III-R IV-R) **13**
   A. The physician director of the emergency department shall be board-certified or board-admissible in emergency medicine. (I-R, II-R) **6, 11, 13**
   B. There shall be a physician trained in stroke care current in cerebrovascular CME in the emergency department twenty-four (24) hours a day (I-R, II-R, III-R) **2, 6, 11, 13**
   C. There shall be written protocols defining the relationship of the emergency department physicians to other physician members of the stroke team. (I-R, II-R, III-R, IV-R) **7, 10, 13**
   D. All registered nurses assigned to the emergency department shall be credentialed in stroke nursing by the hospital within one (1) year of assignment. (I-R, II-R, III-R IV-R) **11, 13**
   E. Registered nurses shall document a minimum of eight (8) hours of stroke-related continuing nursing education per year. (I-R, II-R, III-R IV-R) 11**, 13**
   F. The emergency department shall have written care protocols for triage and treatment of acute stroke patients available to ED personnel and should be reviewed and revised annually. (I-R, II-R, III-R, IV-R) 2**, 10, 13**

2. Equipment for resuscitation and life support with age appropriate sizes shall include the following:
   A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, sources of oxygen and mechanical ventilator I-R, II-R, III-R, IV-R (except mechanical ventilator);

B. Suction devices I-R, II-R, III-R IV-R;
C. Electrocardiograph, cardiac monitor and defibrillator I-R, II-R, III-R, IV-R;
D. Central line insertion equipment-I-R, II-R, III-R, IV-R;
E. All standard intravenous fluids and administration devices including intravenous catheters and IO. I-R, II-R, III-R IV-R;
F. Sterile surgical sets for procedures standard for the emergency department -I-R, II-R, and III-R;
G. Gastric lavage equipment -I-R, II-R, III-R IV-R;
H. Drugs and supplies necessary for emergency care I-R, II-R, III-R, IV-R;
I. Two-way radio linked with emergency medical service (EMS) vehicles-I-R, II-R, III-R, IV-R;
J. End-tidal carbon dioxide monitor--I-R, II-R, III-R, IV-R
K. Temperature control devices for patient, parenteral fluids and blood-I-R, II-R, III-R IV-R;
L. Rapid infusion system for parenteral infusion-I-R, II-R, III-R, IV-R.

3. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R, III-R, IV-R, IV-R)
4. There shall be CT capability with twenty-four (24) hour coverage by technicians.(I-IH, II-IH, III-IA) 2**, 9, 12**

(B) The hospital shall have a designated stroke ICU for stroke center designation. (I-R. II-R) **15**

1. There shall be a designated stroke medical director for the ICU. (I-R, II-R) **5, 15**
2. A physician who is not the emergency department physician shall be on duty in the ICU or available in-house twenty-four (24) hours a day in a level I stroke center. **2, 6, 15**
3. The minimum registered nurse/patient ratio used shall be one to one (1:1) or one to two (1:2). (I-R, II-R)
4. Registered nurses shall have a minimum of ten (10) hours of stroke-related continuing nursing education per year. (I-R, II-R) **11, 15**
5. There shall be beds for stroke patients or comparable level of care provided until space is available in ICU. (I-R, II-R)
6. Equipment for resuscitation and to provide life support for the stroke patient shall be available for the intensive care unit. This equipment shall include, but not be limited to:
   A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator (I-R, II-R)
   B. Oxygen source with concentration controls-(I-R, II-R)
   C. Cardiac emergency cart, including medications (I-R, II-R)
   D. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R)
   E. Electronic pressure monitoring and pulse oximetry (I-R, II-R)
   F. End-tidal carbon dioxide monitor and mechanical ventilators (I-R, II-R)
   G. Patient weighing devices (I-R, II-R)
   H. Drugs, intravenous fluids and supplies (I-R, II-R)
   I. Intracranial pressure monitoring devices (I-R, II-R)
7. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R)

(C) The hospital shall meet post-anesthesia recovery room (PAR) standards for stroke center designation. (I-R, II-R)

1. Registered nurses and other essential personnel who are not on duty shall be on call and available within **sixty (60)** minutes. (I-R, II-R)
2. Equipment for resuscitation and to provide life support for the stroke patient shall include, but not be limited to:

A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen and mechanical ventilator-(I-R, II-R)
B. Suction devices (I-R, II-R)
C. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R)
D. All standard intravenous fluids and administration devices, including intravenous catheters (I-R, II-R)
E. Drugs and supplies necessary for emergency care (I-R, II-R)

(D) The hospital shall have stroke rehabilitation or a written transfer agreement. (I-R, II-R, III-R, IV-R)

(E) Radiological capabilities for stroke center designation including a mechanism for timely interpretation to aid in patient management shall include: **2, 9, 12**
1. Angiography with interventional capability available twenty-four (24) hours a day with a 1 (one) hour maximum response time (I-R, II-R)
2. Resuscitation equipment available to the radiology department-I-R, II-R, III-R;
3. In-house computerized tomography (I-R, II-R, III-R) 9**, 12**
4. Computerized tomography technician (I-IH, II-IH, III-IA) 2**, 9, 12**

(F) There shall be documentation of adequate support services in assisting the patient's family from the time of entry into the facility to the time of discharge. (I-R, II-R, III-R) **23**

(G) The stroke unit of a designated stroke center shall have the following personnel and equipment: (I-R, II-R, III-R) **14**
1. Registered nurses and other essential personnel on duty twenty-four (24) hours a day (I-R, II-R) **2, 14**
2. Equipment for resuscitation and to provide supports for the stroke patient including, but not limited to:
   A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator and sources of oxygen (I-R, II-R, III-R)
   B. Suction devices (I-R, II-R, III-R)
   C. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R, III-R)
   D. All standard intravenous fluids and administration devices and intravenous catheters (I-R, II-R, III-R)
   E. Drugs and supplies necessary for emergency care (I-R, II-R, III-R)
3. Documentation that all equipment is checked according to the hospital preventive maintenance schedule (I-R, II-R, III-R)

(H) The operating room personnel, equipment and procedures of a stroke center shall include, but not be limited to:
1. An operating room adequately staffed in-house twenty-four (24) hours a day (I-R, II-R)
2. Equipment including, but not limited to:
   A. Operating microscope-(I-R, II-R);
   B. Thermal control equipment for patient, parenteral fluids and blood (I-R, II-R)
   C. X-ray capability- (I-R, II-R)
   D. Instruments necessary to perform an open craniotomy-(I-R, II-R)
   E. Monitoring equipment-(I-R, II-R)
3. Documentation that all equipment is checked according to the hospital preventive maintenance schedule-I-R, II-R, III-R;

(I) The following clinical laboratory services shall be available twenty-four (24) hours a day: **2, 24**
1. Standard analyses of blood, urine and other body fluids-(I-R, II-R, III-R, IV-R) 24
2. Blood typing and cross-matching—(I-R, II-R, III-R) **24**
3. Coagulation studies—(I-R, II-R, III-R, IV-R) **24**

4. Comprehensive blood bank or access to a community central blood bank and adequate hospital blood storage facilities- (I-R, II-R, III-R) **24**
5. Blood gases and pH determinations- (I-R, II-R, III-R, IV-R) **24**
6. Blood chemistries (I-R, II-R, III-R, IV-R) **24**

(4) Standards for Programs in Performance Improvement Patient Safety Program, Outreach, Public Education and Training for Stroke Center Designation.

(A) There shall be an ongoing performance improvement and patient safety program designed to objectively and systematically monitor, review and evaluate the quality, timeliness and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems. (I-R, II-R, III-R IV-R) **1, 2, 21**

(B) The following additional performance improvement and patient safety measures shall be required:

1. All stroke centers shall collect, trend and electronically report to the Department key data indicators as identified by Department of Health and Senior Services. (I-R, II-R, III-R, IV-R) **1, 21**
2. Regular reviews of all stroke-related deaths—(I-R, II-R, III-R, IV-R) **1, 21**
3. A regular morbidity and mortality review, at least quarterly-(I-R, II-R, III-R, IV-R) **1, 21**
4. A regular multidisciplinary stroke meeting that includes representation of all members of the stroke team, with minutes of the meetings to include attendance, adherence to the stroke protocol and findings-I-R, II-R, III-R, IV-R; **1, 7, 10, 19, 21**
5. Regular reviews of the reports generated by the Department of Health and Senior Services from the Missouri stroke registry (I-R, II-R, III-R, IV-R) **1, 21**
6. Regular reviews of pre-hospital stroke care including inter-facility transfers **(**I-R, II-R, III-R, IV-R) **1, 21**
7. Participation in EMS regional systems of stroke care as established by the Department of Health and Senior Services (I-R, II-R, III-R, IV-R)
8. Stroke patients remaining greater than six (6) hours prior to transfer will be reviewed as a part of the performance improvement and patient safety program. I-R, II-R, III-R, IV-R. **1, 2, 21**

(C) A neurology outreach program shall be established to assure twenty-four (24) hour availability of telephone consultation or telemedicine with physicians in the outlying region. (I-R, II-R) 2**, 6, 8**

(D) A public education program shall be established to promote stroke prevention and signs and symptoms awareness and to resolve problems confronting the public, medical profession and hospitals regarding optimal care. (I-R, II-R,III-R) **20**

(E) The hospital shall be actively involved in local and regional EMS systems by providing training and clinical resources. (I-R, II-R, III-R)

(F) There shall be a hospital-approved procedure for credentialing nurses in stroke care. (I-R, II-R, III-R, IV-R) **11**

1. All nurses providing care to stroke patients and assigned to the emergency department or ICU shall complete a minimum of sixteen (16) hours of stroke nursing courses to become credentialed in stroke care. (I-R, II-R, III-R, IV-R) **2, 11, 15**
2. The content and format of any stroke nursing courses developed and offered by a hospital shall be developed in cooperation with the stroke medical director. A copy of the course curriculum used shall be filed with the HSL. (I-R, II-R, III-R, IV-R)

(G) A hospital diversion protocol must be maintained in accordance with state regulations. This protocol is designed to allow best resource management within a given area. This protocol must contain a defined performance improvement and patient safety process to review and validate established criteria within that institution. Hospital diversion information must be maintained to include date, length of time and reason for diversion.

(5) Standards for the Programs in Stroke Research for Stroke Center Designation.

(A) The hospital and its staff shall support a research program in stroke as evidenced by any of the following: **3, 18**

1. Publications in peer reviewed journals--I-R; **18**
2. Reports of findings presented at regional or national meetings--I-R; **18**
3. Receipt of grants for study of stroke care--I-R; and **18**
4. Production of evidence based reviews--I-R. **18**

(B) The hospital shall agree to cooperate and participate with the DHSS in conducting epidemiological studies and individual case studies for the purpose of developing stroke prevention programs. (I-R, II-R, III-R, IV-R) **3, 18**

AUTHORITY

**Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002 and 190.241, RSMo 1987 amended 1998.*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions

PRIVATE COST: This proposed amendment will cost private entities

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Kimberly O'Brien, Director, Department of Health and Senior Services, Division of Regulation and Licensure, PO Box 570, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.

Hospital STEMI Work Group
Criteria for STEMI Center Designation
January 6. 2009 Discussion Document
Group accepted changes 1/6/09

CRITERIA	LEVEL I	LEVEL II	LEVEL III
I. STEMI Center Volumes:			
1. Total number of elective Percutaneous Coronary Interventions (PCI) /year/ center	400	200	
2. ~~75+ PCI procedures/year/physician~~ move to staff req./recommendations	~~x~~	~~x~~	
3. Primary PCI (PPCI)/Year/center	> 49	> 36	
~~4. Annual Hospital STEMI patient volume~~	~~85-90~~	~~60-65~~	
II. STEMI Center Hospital Capabilities:			
1) STEMI Program	X	X	X
a) STEMI Medical Director-board certified, job description, org chart showing relation to other departments, oversee staffing, assure training CEUs for staff and CMEs/year for physicians,	X	X	X
b) STEMI Program Manager (RN or qualified individual)	X	X	X
c) STEMI Team			
i. Physician experienced in diagnosing and treating cardiovascular disease and STEMI (available 24/7)	X	X	X
ii. Another health care professional credentialed in STEMI as determined by hospital (available 24/7)	X	X	X
d) Representation from hospital administration, EMS, ED, ICU, pharmacy, cardiac cath lab, CVD-MI unit, rehabilitation, discharge planning, laboratory, nutrition services	X	X	
2) Availability of hospital departments/services to support STEMI care			
a) Emergency Department	X	X	X
b) Intensive Care Unit	X	X	
c) Inpatient areas	X	X	X
d) General standards for staffing and competencies of these areas	X	X	X
3) **Time Frame** for availability of services (IH = in house; IA = 20 minutes; PA = 30 minutes)			
a) 24/7 Emergency Department with physician access			

CRITERIA	LEVEL I	LEVEL II	LEVEL III
b) 24/7 CATH Lab, angiography and interventional capabilities available	PA	PA	
c) 24/7 Coronary Artery Bypass Graft (CABG)	PA		
d) Core STEMI Team Members	PA	PA	PA
e) 24/7 **Clinical Laboratory** to provide necessary testing and results	x	x	x
f) **One call activation for cath lab**	x	x	
g) One call access to transfer STEMI			x
h) Access to cardiac rehab	x	x	x
i) 24/7 **Surgical Backup (regs will define specific equip needed)**	x		
III. Hospital protocol for pre-hospital and STEMI Team Communication			
1. EKG, system for communication between hospital and EMS staff 24/7, link to EM system that provides hospital diversion status	x	x	x
2. Mechanism in place for activation of Cardiac Cath lab team at time of EMS STEMI identification	x	x	x
IV. Hospital protocol for rapid transfer from non-PCI facility (when appropriate)			
1. **Accept all** STEMI transfers	x	x	
2. ~~Formal~~ Written **agreement** with Level I/Level II STEMI Center to transfer and accept complex patients	x	x	x
3. A rapid transfer **process** in place with higher level of STEMI care		x	x
4. A hospital diversion protocol must be maintained in accordance with state regulations… (in current trauma regulations. This will need to be validated with legal teams and risk managers.)	x	x	x
V. Hospital protocol for care and coordination			
1. Agree to accept all STEMI patients appropriate for the level of care provided at the hospital, regardless of race, sex, creed or ability to pay	x	x	x
2. Staff credentialed in STEMI (see credential section.)	x	x	x
3. Protocol for cardiac rehabilitation—Phase I is in-house	x	x	

IH-In-house, IA-Immediately Available (within 20 min.), PA-Promptly Available (within 30 min.)

CRITERIA	LEVEL I	LEVEL II	LEVEL III
VI. Hospital capacity to support STEMI patient discharge transition back to community and/or rehabilitation facility if needed.			
1. Arrangement/ discharge plan for the provision of cardiac rehabilitation post discharge—part of discharge documentation. Protocol for discharge transition back to care and oversight by Primary Care Physician (PCP) or rehabilitation facility if needed (coordinate with existing procedures) o Secondary prevention o Discharge planning	x	x	
2. Arrangement/ discharge plan for the provision of repatriation to community hospital if indicated			
3. Timely feedback (recommend within 72 hours) for sending and receiving facilities/EMS providers. ~~Call within 24 hours followed with written notice within 72 hours (this is reference to EMS providers)~~	x	x	
VII. Personnel Education/Credentials:			
1. RN credentialing for STEMI care	x	x	x
2. Medical Director CEU hours	x	x	x
3. Emergency Department RN CEUs	x	x	x
4. Minimum CEU requirements for ED	x	x	x
5. Minimum CEU for Cath Lab staff	x	x	
6. STEMI Program Manager CEUs	X	X	X
7. Interventional Cardiologist (75+ PCI/phys/year recom)			
VIII. Community Education:			
1. Public education program for STEMI signs/symptoms, emergency transport, STEMI treatment and center service availability	x	x	
2. Ability to collect and report data to STEMI registry & DHSS	x x	x x	x x
3. Cardiology outreach program for 24 hour phone consults	x	x	

IH-In-house, IA-Immediately Available (within 20 min.), PA-Promptly Available (within 30 min.)

	CRITERIA	LEVEL I	LEVEL II	LEVEL III
IX.	**Research:** Pick preferred language:			
	a. The STEMI medical director shall participate in the STEMI center's research and publication projects (this wording parallels language in stroke and trauma center designation regulations) and/or *Institution will conduct or participate in research study that is under auspices of IRB oversight either at that facility or cooperative facility This language from 12/2 discussion* *and* b. The hospital and its staff shall support a research program in STEMI as evidenced by any of the following • Publications in a peer review journal • Reports of findings presented at regional and/or national conferences • Receipt of grants for study of STEMI care • Production of evidenced based reviews. *(This language from 12/2 discussion and in stroke and trauma regulations)* *c. The* hospital shall agree to cooperate and participate with the DHSS in conducting epidemiological studies and individual case studies for the purpose of developing stroke prevention programs. *(This language from 12/2 discussion and in stroke and trauma regulations)*	X X X	X	X
X.	**Participate in Quarterly regional STEMI conferences**	**x**	**x**	**x**
XI.	**Performance Metrics:**			
	~~1. PCI within 60 +/- 30 minutes of arrival (75-80% of time) (need data set to evaluate appropriate x% of time; may need to consider timeframe for this criteria; time is based on first medical contact time. Challenge in view of current data based on D2B time. Must evolve metric to reflect time from symptoms to time to definitive care.)~~ Device or balloon within 90 ~~+/- 30~~ min from first medical contact ~~facility arrival~~ or field EKG STEMI diagnosis (75% of time)	~~X~~ X	~~X~~ X	
2.	Patient presentation—do different metrics based on whether patient is walk-in, transfer, versus EMS transport, time for EMS transfers from one hospital to higher level when needed. (Starting point for next meeting discussion)			
3.	Lytics within 30 minutes of first medical contact or arrival (75-80% of time)			x
4.	Formal STEMI/AMI CQI process	x	x	x

IH-In-house, IA-Immediately Available (within 20 min.), PA-Promptly Available (within 30 min.)

	CRITERIA	LEVEL I	LEVEL II	LEVEL III
5.	Immediate (define) feedback to the transfer hospital and EMS	x	x	
6.	Competencies for the practitioner, nurse and physician	x	x	x
7.	State Registry reporting	x	x	x
8.	ACC guidelines/registry	x	x	x
9.	Quality vs. what for EMS to decide which place to go			
10.	Risk adjusted mortality			
XII.	**Financing**			
	Further discussion needed on reimbursement issues and assurances for adequate financing of agencies and facilities within STEMI-TCD system			

IH-In-house, IA-Immediately Available (within 20 min.), PA-Promptly Available (within 30 min.)